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From: wanda@lawfund.org
Received: from healthworld.com ([205.180.191.2]) 6918 '99 MAR 11 NO:13
by smtp3.nwnexus.com (8.8.8/8.8.8) with ESMTP id NAA08207
for <citizens@verycosmic.com>; Mon, 10 Aug 1998 13:17:34 -0700 (PDT)
Received: from mail pickup service by healthworld.com with Microsoft SMTPSVC;
Mon, 10 Aug 1998 13:13:46 -0700
To: <citizens@verycosmic.com>
Subject: Write to Know
Date: Mon, 10 Aug 1998 13:12:45 -0700
X-MimeOLE: Produced By Microsoft MimeOLE V4.72.2106.4
Message-ID: <003754613200a88WEBSEVER@healthworld.com>
Status:

LETTER TO FDA
Dockets Management Branch (HFA-305)
Food and Drug Administration
ATTN: Docket #98N-0044
c/o Michael Friedman, M.D.
Lead Deputy Commissioner
5630 Fishers Lane, Room 1061
Rockville, MD 20857-0001

Dear Dr. Friedman,

I am writing to notify you that FDA's proposed rulemaking on structure/function claims, 21 CFR Part 101/Docket#98N-0044, is totally unacceptable to me as an American consumer of dietary supplements. Any final rule must reflect the true meaning and intent, mandated by Congress, of the Dietary Supplement Health and Education Act (DSHEA) of 1994. I support FDA's effort to fully implement DSHEA as intended by Congress, however I strongly object to the proposed regulations which:

- 1.) limit my access to (scientific) information about dietary supplements and health, and
- 2.) redefine disease restricting my ability to focus on preventive care and wellness.

It is extremely important to preserve Section 6 of DSHEA to allow for a robust flow of valuable health information in the marketplace.

I want free access to available information about dietary supplements and health, and I want FDA to withdraw its proposal to redefine disease in a way that limits such health information.

DSHEA allows products to make structure/function claims on the product labels. Redefining disease to nullify that part of DSHEA must be withdrawn.

Herbal remedies and supplements are not drugs. The FDA has no business inserting itself into this issue. We know this is about money and not health. If individuals using herbs were being helped by the AMA and the FDA, there would be no need for "alternatives." I will resist with every tool available, any effort to limit or restrict my right to choose herbs and to educate myself about their uses in maintaining a high level of health and well-being!!!!!!

Sincerely,
Wanda Gray
wanda@lawfund.org
98N-0044

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